GUIDELINES
SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE (SPOREs) IN PANCREATIC CANCER

ORGAN SYSTEMS BRANCH
OFFICE OF CENTERS, TRAINING, & RESOURCES
OFFICE OF DEPUTY DIRECTOR FOR EXTRAMURAL SCIENCES
NATIONAL CANCER INSTITUTE

January 2002
Version 2/20/02

Quick Links
GUIDELINES: Page 1
Popular Grant Mechanisms
Frequently Asked Questions
E-mail: NCI Referral Officer
Special Populations
Grant Funding Resources

SECTION I. GENERAL GUIDELINES

A. INTRODUCTION

Specialized Programs of Research Excellence (SPOREs) were conceived and implemented by the National Cancer Institute (NCI) through a special $20 million appropriation from Congress in Fiscal Year 1992. SPOREs evolved from the original NCI Organ Site Programs, which were organ-specific but without translational research focus, established shortly after the National Cancer Act of 1971. SPOREs represented a strategic response to the rapid expansion of information about cancer being developed through basic research using model systems. At that time, there was no funding mechanism designed exclusively to focus on translational research that would take a systematic approach to exploring which basic research discoveries were potentially the most likely to have an impact on human cancers. In order to address this need, the SPORE Program was initiated by the NCI as an experiment to promote interactions between basic scientists and applied scientists and provide them with the flexibility to rapidly test new approaches to the prevention, early detection, diagnosis and treatment of human cancer.

When the SPORE program was initiated in FY92, Request for Applications (RFAs) were issued that resulted in the funding of four breast cancer SPOREs, two prostate cancer SPOREs and two lung cancer SPOREs. The objective of the SPORE program was and is to encourage a wide range of scientific approaches focused on translational research (see the SPORE definition of translation below). Of particular importance was choosing a grant mechanism (i.e., the P50) that has all of the features necessary to enable SPOREs as translational research instruments. These P50 grants are designed so that every research project is inherently translational: specialized infrastructures are established to support translational research; scientists work as teams rather than as independent investigators; scientists have the flexibility to start and stop research projects without additional peer review; scientists have flexible funds to develop pilot projects and test new technologies in collaboration with scientists in or outside of their institutions; and SPOREs combine their resources to ask questions that no one institution could address alone.

The first P50 SPORE grants were funded for three rather than five years in order to ensure that the translational research concept was working; as the experiment proved more promising, all applicants were allowed to request five years of support. Using the RFA process, the SPORE Program evolved to include five sites: breast, prostate, lung, gastrointestinal and ovary. However, by limiting the submission of SPORE applications to every five years in response to RFAs, the Program was relatively “closed” and unable to capitalize on investigator-initiated scientific opportunities. In addition, the Program was not open to all cancer sites. These issues were discussed with NCI advisory groups. In particular, the NCI Board of Scientific Advisors suggested that the initial results of the SPORE Program were very promising and, although it favored additional evaluation with time, it saw no reason to restrict the expansion of the SPORE Program. As a result, in 1999 the NCI approved restructuring the SPORE program from one that was RFA-driven to one that was investigator-initiated, utilizing a program announcement (PA) open to grant applications for all types of cancers on a scheduled competitive basis.

The guidelines presented here were specifically formulated to provide information to applicants responding to TPA-02-038, Specialized Programs of Research Excellence (SPOREs) in Pancreatic Cancer for the Year 2002, which is a one-time solicitation with a receipt date of October 1, 2002. Pancreatic cancer strikes approximately 29,000 persons in the United States each year, and an equivalent number die from this disease. Despite this almost universal fatality, research has lagged behind that focusing on more common cancer sites and there has been a dearth of new investigators entering the field. Genetic and environmental risk factors, as well as the natural history of the disease, are poorly understood, making development of appropriate preventive and therapeutic strategies difficult. This has been due, at least in part, to lack of accessibility to high-risk patients and kindreds and specimen banks of normal, precancerous, and cancerous human pancreatic tissues; lack of suitable experimental model systems; and historically lower levels of financial support for research (see Pancreatic Cancer: An Agenda for Action, Report of the Pancreatic Cancer Progress Review Group, http://planning.cancer.gov/prg_assess/prg/panprg/pancreaticcprg1.htm). SPOREs in Pancreatic Cancer are intended to address these deficiencies in the context of translational research, however some of the requirements applicable to SPOREs in other organ sites have been modified to encourage participation and collaboration, spur progress in basic research, and allow time for the field to mature.

The ultimate goal of these SPOREs is to reduce the pancreatic cancer incidence, morbidity, and mortality. To

accomplish this, it will be necessary to assemble a critical mass of laboratory and clinical scientists who will work together to extend the scientific information base in this disease and translate findings to applied innovative research with patients and populations. Specific objectives for SPOREs in Pancreatic Cancer are to: 1) build the capacity for interdisciplinary translational research in pancreatic cancer, 2) establish consortia to ensure appropriate access to pancreatic cancer patients and tumor tissues and promote the development of pancreatic cancer family registries, 3) expand the research foundation in pancreatic cancer via development and improvement of animal and in vitro model systems that can be translated into human disease applications; 4) foster collaborations between basic and clinical or applied research scientists; 5) provide career development opportunities in translational pancreatic cancer research for both junior investigators and established scientists wishing to refocus their careers; and 6) develop extended collaborations in critical areas of research need with laboratory, clinical, and population scientists in the parent and other institutions.

Applicants funded under TPA-02-038 will be expected to meet standard SPORE Guidelines requirements at the time a competing renewal application is submitted.

---

top

B. SPORE DEFINITION OF TRANSLATIONAL RESEARCH

There is currently no consensus definition of translational research. For purposes of the SPORE program the NCI defines it as follows: **translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans AND/OR determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer**. The term “interventions” is used in its broadest sense to include molecular assays, imaging techniques, drugs, biologicals and/or other methodologies that are relevant to the prevention, early detection, diagnosis, prognosis or treatment of cancer. Translational research in SPOREs is always founded on and directly connected to some aspect of human biology and may encompass any form of cellular, molecular, structural, biochemical, genetic, or other appropriate experimental approach.

For the purpose of this pancreatic cancer initiative, proof of principle in animal models or in vitro systems within the 5-year term of the grant award are acceptable, but the clinical or applied perspective must be evident in the conceptualization and development of proposed research projects and there must be potential to study human endpoints within a reasonable time frame. Similarly, studies that seek to determine the biological basis for an observation in human cancer should do so within five years. Some, but not all, types of behavioral research are appropriate for SPOREs. Bio-behavioral research that clearly focuses on links between biological variables, processes, and mechanisms pertaining to behavior or psychosocial variables is appropriate. Psychosocial variables might include cognitions, affect, personality, or interpersonal context or processes (e.g., social support, familial interactions, physician-patient communication). Behavioral research that focuses on psychosocial processes or behavior change without a clear, specific linkage to a biological process (e.g., disease susceptibility, etiology, or progression) is not appropriate. SPOREs are also not the place for definitive validation of new interventions, which are supported by other programs in several divisions of the NCI.

Within the limits of the definitions and time frames outlined above, SPOREs have considerable flexibility in selecting and developing areas of research with the greatest anticipated potential for improving cancer outcomes. Investigators who question whether their research goals adhere to the above definition of translation and/or the expectations of the SPORE Program are advised to consult with NCI program staff in the Organ Systems Branch.

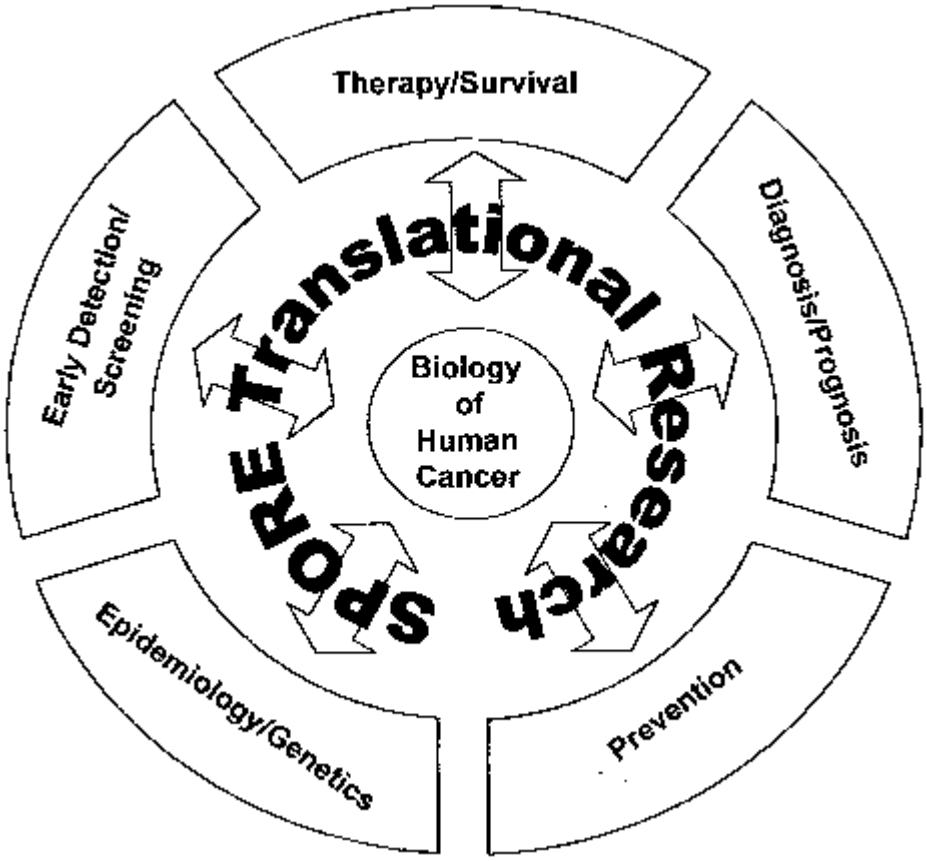

Figure 1. Translational research focus of a SPORE. Research projects should be designed to (a) test the relevance of a biological discovery in human cancer risk, prevention, diagnosis, prognosis, or treatment or (b) determine the biological basis of an observation made in the clinic or population within the five-year term of the grant.

---

top

C. GENERAL DESCRIPTION OF THE SPORE PROGRAM

Specialized Programs of Research Excellence (SPOREs) utilize the P50 grant mechanism to support interdisciplinary teams of investigators who are dedicated to translational research focused on an organ-specific human cancer (e.g., breast cancer) or a highly related group of human cancer types (e.g., gastrointestinal). SPOREs are open to any scientific approaches that can have an impact on the disease and are dependent upon team approaches in the design and implementation of the research. SPOREs differ from program project grants (P01s) in that SPORE grants focus on human disease and exclusively support translational research, have a flexible approach to starting and stopping research projects, and have a required tissue bank core as well as required programs for career development and developmental projects. In addition to their organ-site orientation, the common features of all SPOREs are the following:

1. **Translational Research Focus**
   All SPOREs focus on translational research that meets the definition provided in Section I.B. above. The research of a SPORE is dedicated to obtaining experimental results that will have a direct impact on improving approaches to the prevention, detection, diagnosis and/or treatment of human cancer. Pancreatic SPOREs may support basic science projects if the objective of the research will be directly relevant to human cancer. If a project has lost its translational focus or the likelihood of having an impact on human cancer, it should be discontinued and another funding source sought.

2.

Every project in a SPORE is inherently translational because it is collaboratively designed and executed by basic scientists working at the cellular and molecular levels, physicians experienced in patient-oriented research, and population scientists experienced in studying the patterns of disease.

3. **Flexibility to Change Research Direction/Team Approach**
   SPOREs continually select the most promising research approaches that are likely to have a more immediate impact on improving cancer prevention, detection, diagnosis, prognosis and/or treatment. The flexibility of the SPORE program promotes the discontinuance of research projects demonstrating little or no translational significance or scientific progress and enables new projects with greater potential to be initiated. While the team of scientists that participates in the SPORE remains largely the same, the lead roles of co-investigators on projects may change through the course of the research.

4. **Specialized Research Infrastructure**
   SPOREs are expected to develop the critical research infrastructure needed to sustain translational research objectives for projects within the SPORE, as well as for potential collaborative research with other SPOREs and other research groups within the biomedical research community. SPOREs are expected to be in a position to facilitate the complex research objectives inherent in studying human cancer.

5. **Fostering Translational Research Careers**
   SPOREs provide a unique environment for translational research that can be used to prepare new scientists for careers in this evolving field or provide the opportunity for established scientists to re-orient their research careers toward translational research.

6. **Research Collaborations, Networks, and Consortia**
   SPOREs are expected to identify the kinds of research questions that can only be accomplished through research collaborations, networks, and consortia. SPOREs collaborate with other scientists in the field to answer research questions that can take full advantage of SPORE scientific expertise and infrastructure. Through the promotion of Inter-SPORE research, SPOREs also conceive and initiate research that is linked to other key programs of the NCI.

7. **Sharing Information** SPOREs readily share information within their organ site network, as well as with other SPOREs, to take advantage of research results that are applicable to various cancer sites.

---

top

D. FUNDING OF SPORE GRANTS

1. **Grant Mechanism**
   Support of this program is through the specialized center grant (P50) mechanism employed by the National Institutes of Health. Applicants are responsible for the planning, direction, and execution of the proposed SPORE program. Awards can be made for up to five years and will be administered under NIH grants policy as stated in the NIH Grants Policy Statement.

2. **Basis of Funding**
   Applications will be awarded on a competitive basis. The following will be considered in making decisions: quality of the application as determined by peer review, availability of funds, and programmatic priorities.

3. **Planning Grants**
   While applicants cannot apply directly for planning grants (P20s), under special circumstances, the NCI may consider funding a P50 SPORE application at a reduced level for up to two years using the P20 grant mechanism. Circumstances leading to the funding of a P20 rather than a P50 include: (1) the research projects in the SPORE application have high scientific merit but other essential components of the

application require further development; (2) the peer review criticisms can be readily addressed within two years; and/or (3) the application meets important NCI program objectives (e.g., the organ site to be studied is under-represented).

4. **Expanded Authorities**
   Both NCI P50 and P20 grants may be administered by the awardee under Expanded Authorities which can be viewed at: http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#expandauth. The expanded authorities allow additional flexibility to take advantage of research opportunities as they arise throughout the term of the grant. Under the expanded authorities, NIH has waived the requirement for its approval of specified actions under certain awards and has provided the authorities to grantees to take such actions without NIH prior approval. These actions include the carryover of unobligated funds and extensions of the project period without additional funds.

---

top

E. ELIGIBILITY AND REQUIRED COMPONENTS

Applications must meet all of the following eligibility criteria [items 1(a)-(d)] as well as contain the required components of a SPORE listed in items 2-9 below. Applications that are not responsive to these requirements will be returned to the applicant by NCI program staff and will not undergo scientific peer review.

1. **Eligibility**

   a. *Institutional*
   Applications may be submitted by domestic for-profit and non-profit organizations, either public or private, including universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

   b. *Minimum Research Base*
   In order for a SPORE application to be accepted by NCI, the application must include two or more independent investigators who currently serve as principal investigators (or project leaders) on peer-reviewed research grants (e.g., R01, P01, U01, U10, ACS, DOD, or equivalent) in pancreatic cancer (or pre-malignant lesions of the pancreas) or who have published in pancreatic cancer research in peer reviewed journals within the last three years, and who will serve an active role in the Pancreatic Cancer SPORE. The applicant is encouraged to provide a separate list of these grants

   c. *Cancer Patient Population*
   Each SPORE must document access to a pancreatic cancer patient population in the cancer-site focus of the application and provide reasonable assurance that the patients and tissues needed for translational pancreatic research are readily available. Consortium agreements that cross institutional boundaries are encouraged to assure adequate access to pancreatic cancer patients and tissues.

   d. *Budget Limitation*
   By NCI policy, all competing SPOREs are subject to both direct cost and total cost budget caps, which currently are $1.75 million and $2.75 million, respectively. These caps may be exceeded by applicants for SPOREs in Pancreatic Cancer for the additional costs associated with establishing consortia for collecting and distributing pancreatic cancer tissue and establishing family registries; caps may not be exceeded for any other purpose. In non-competing years, applications can exceed these caps as a result of standard (yearly) cost-of-living increases or as a result of special supplements approved by the NCI. For more information about the cap in any given year, applicants

must contact the Organ Systems Branch using the telephone number, fax number or e-mail address listed under INQUIRIES below.

2. **Statement of Institutional Commitment**
An institution considering applying for a SPORE should demonstrate a commitment to the SPORE's stability and success by incorporating the SPORE high within its institutional priorities. The application must provide a statement of commitment that includes a plan addressing how the institutional commitment will be established and sustained, how the institution will maintain accountability for promoting scientific excellence, and how the SPORE research effort will be given a high priority within the institution relative to other research efforts. The institutional commitment may be in the form of support for recruitment of scientific talent, provision of discretionary resources to the SPORE Director, assignment of specialized research space, cost sharing for resources, or other ways proposed by the applicant institution. A letter from the Dean or Cancer Center Director should be attached confirming this commitment. In the case of a SPORE that involves a consortium arrangement between two or more institutions, the institution that submits the P50 application must receive a formal written agreement(s) from the other participant organization(s). This agreement should clearly delineate the institutional commitment of the participating organization(s) (in the ways outlined above) to the SPORE program.

3. **Intellectual Property Rights**
The institution should provide a written assurance that it will protect the intellectual property rights of the SPORE investigators and their collaborators and under no circumstances engage in formal/legal agreements with commercial sources (e.g., pharmaceutical companies) that would compromise the ability of SPORE investigators to have unhampered access to institutional resources in SPORE-related research or participate fully in collaborations with any other researchers. The statement of commitment should also include a written assurance that in its interactions with commercial entities under sponsored research agreements, the SPORE will comply with the requirements of the Bayh-Dole Act and NIH funding agreements while upholding basic principles of academic freedom. Sponsored research agreements with commercial entities should be entered into by the SPORE only upon due consideration of the points outlined in "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts (Federal Register, Vol. 59, No. 215, Tuesday, November 8, 1994, pp. 55674-55679)", a copy of which can be viewed at: http://ott.od.nih.gov/NewPages/text-com.htm. The statement of commitment should also include a written assurance that the SPORE will manage its interactions with third parties so that they do not restrict the SPORE's ability to receive and disseminate biomedical research materials from and to the scientific community. Likewise, letters should be supplied by any relevant third parties confirming their adherence to these policies.

4. **Research Projects**
All research projects must focus on pancreatic cancer. Research projects may be conducted solely through the parent institution, or through collaborative associations that have been developed or are planned with other SPOREs or with other investigators in the biomedical research community. Projects with foreign components or full projects at foreign sites are encouraged when they enhance the scientific and translational potential of the SPORE. However, all SPOREs must meet the following requirements:

   a. Each proposed research project must be in accord with the definition of translational research as described in Section I.B above. Investigators who are not certain about whether their project fits this definition are advised to consult with NCI staff.

   b. Research projects may have human endpoints or endpoints in an animal or in vitro model within the 5-year term of the grant. Basic research projects, such as those employing animal models or cell lines therefore qualify, but the potential for translation into the applied or clinical setting should be in the foreseeable future. Long-term basic research projects, with no foreseeable human application or translational endpoint, are not appropriate. Applicants are encouraged to contact the Organ Systems Branch (see INQUIRIES below) if they have any questions concerning this essential

requirement.

c. Each proposed research project must be led by co-(principal) investigators in biological science and applied sciences who commit adequate percent efforts and who use their combined conceptual and experimental skills in designing and implementing the project. It should be evident from this collaboration that translational research, or the potential for generating new hypotheses relevant to translational research in pancreatic cancer, will be accelerated. It is not necessary that the co-investigators commit equal effort to the project. There are NO exceptions to this requirement.

d. A research project focusing on early detection, screening, prevention, and/or population science research is encouraged, but not required.

e. A minimum of three research projects are required representing a balance and diversity of research objectives (e.g., screening, prevention, diagnosis, treatment). Applications with a specific theme (e.g., gene therapy in pancreatic cancer) are discouraged. (Note that three projects scored by the peer review group will be required for award, see REVIEW CONSIDERATIONS, Sections G.1. and G.5. below.)

f. A plan must be proposed for evaluating the scientific progress and translational potential of all projects and replacing them as necessary. During the period of award, replacement projects will be reviewed by the grantee institution and NCI program staff, but will not undergo additional peer review. Competing renewal applications will be evaluated based on their track record for fostering significant translational research during the prior grant period.

g. Research projects involving **HUMAN SUBJECTS** must include women, children, and members of minority groups and their subpopulations unless a clear and compelling rationale establishes inclusion is inappropriate with respect to the health of the subjects, the purpose of the research, or another extenuating circumstance. Applicants are required to address this issue in developing a research design appropriate to the scientific objectives of their study. Instructions for responding to this issue are provided at: http://grants.nih.gov/grants/funding/phs398/section_3.html#humans and http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm. Recruitment plans, as well as Gender and Minority Inclusion Reports must be included for each project/ resource that involves human subjects.

Only early (Phase I and Phase II) clinical trials may be supported by the SPORE mechanism. Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998:).

Clinical trials supported or performed by NCI require special considerations. The method and degree of monitoring should be commensurate with the degree of risk involved in participation and the size and complexity of the clinical trial. Monitoring exists on a continuum from monitoring by the principal investigator/project manager or NCI program staff or a Data and Safety Monitoring Board (DSMB). These monitoring activities are distinct from the requirement for study review and approval by an Institutional review Board (IRB). For details about the Policy for the NCI for Data and Safety Monitoring of Clinical trials see: .
For Phase I and II clinical trials, investigators must submit a general description of the data and safety monitoring plan as part of the research application. See NIH Guide Notice on “Further Guidance on a Data and Safety Monitoring for Phase I and II Trials” for additional information: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html.

Information concerning essential elements of data safety monitoring plans for clinical trials funded by the NCI is available:
http://www.cancer.gov/clinical_trials/doc_header.aspx?viewid=a7fbcf28-458e-4f1b-a8e4-5d9c4a917

A copy of the trial protocol, along with informed consent forms, are also required if the trial is already underway or is anticipated to begin soon after an award is made. If the trial will be performed during the latter part of the grant term, submission of these items to NCI program staff is required prior to the initiation of the trial.

The NIH now also requires that all investigators proposing research involving human subjects are educated on the protection of human research participants. This policy was effective as of October 1, 2000 and was published in the NIH Guide for Grants and Contracts, June 5, 2000 (Revised August 25, 2000) which is available at:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

5. **Shared Resources (or Cores)**

   a. Each SPORE must have a dedicated component for collecting and distributing human pancreatic cancer tissue. The tissues may be frozen or archived paraffin blocks, slides, or fluids such as serum, plasma, urine, or sputum samples. This should be a true tissue resource – or integrated and coordinated consortium of resources across multiple institutions - that can be used to generate and test translational hypotheses, rather than a small collection of heterogeneous samples. The tissue core should also include the essential pathological, clinical and family history information needed for conducting a wide range of translational pancreatic cancer research. Appropriate informatics capability for tracking, as well as linkage to clinical and follow-up data sets, should be demonstrated.

      Use of the tissue core in proposed research projects is not required in instances where access to tissue is limited. If tissue resources are already available, however, their use in proposed projects is highly encouraged. While tissue collection may not directly benefit research projects proposed in the SPORE application, this resource should ultimately benefit the specific research activities of the SPORE, as well as the research activities of other scientists within and outside the parent institution who are concentrating on pancreatic cancer research issues. A plan must be proposed for prioritizing distribution of tissues to SPORE scientists and others based on the merit of pancreatic cancer research projects.

   b. (b) Additional shared resources (e.g., administrative, clinical, statistical, animal) may also be proposed that are supportive of one or more of the research projects of the SPORE. Development of pancreatic cancer family registries, or participation in existing registries, is encouraged, even if there is no direct benefit to research projects proposed in the application.

6. **Developmental Research Program**
   Every SPORE must allocate a significant effort to support pilot projects that take maximum advantage of new research opportunities. Such projects may be collaborative among scientists within one or more SPOREs, or with scientists outside the SPORE environment. The SPORE application should propose an institutional review process for funding pilot projects that generate feasibility data and have the most promising translational research potential. These funds are intended to remain flexible and to support studies of a limited duration, e.g., two years or less. The expectation is that successful feasibility studies will replace full projects that are not progressing satisfactorily with regard to research objectives within the SPORE (see above). New applicants may supply a short description (1-2 page(s) maximum) of eligible projects as examples. Renewal applicants should supply their track record of funding pilot projects, ongoing pilot projects, and short descriptions of other potentially eligible projects.

A Developmental Research Program, as a required element of a SPORE, must be maintained throughout the entire term of the grant.

7. **Career Development Program**
   Due to the dearth of investigators in this field, the SPORE must demonstrate a consistent and significant commitment to a career development program in translational pancreatic cancer research. This may focus on post-doctoral candidates, junior faculty, or established investigators who wish to develop or refocus their careers on translational research. Use of career development funds for salary and other support of scientists in the latter category is particularly encouraged. SPORE career development programs are not intended for predoctoral candidates. Funds may be allotted for advertising and soliciting candidates.

   An appropriate portion of the total SPORE budget should be dedicated to this program and support the salary and research costs of candidates with outstanding potential. Each candidate should have a mentor(s) and devote a significant percentage of his/her effort to translational research. The description of this program should include the policies, criteria, and processes for selecting candidates, including special efforts to recruit qualified women and minorities. The plan should include the number and types of positions (e.g., advanced post-docs, junior faculty, established investigators) that will be made available, the criteria for eligibility and selection of candidates, and a description of the selection process. New applicants should provide a list and short description of potential candidates, as well as the names and research activities of mentors. Renewal applicants should provide this in addition to the track record of candidates supported on the SPORE.

   A Career Development Program, as a required element of a SPORE, must be maintained throughout the entire term of the grant.

8. **Annual SPORE Workshop**
   SPORE investigators will be expected to participate in an annual workshop organized by the Organ Systems Branch of the NCI to share positive and negative results with other SPOREs, share materials, assess progress, identify new research opportunities, as well as establish interactions, research priorities, and collaborations that will maximize the impact of the research on reducing incidence and mortality, and improving survival. Travel funds for the Principal Investigator and selected SPORE investigators and collaborators may be budgeted for this purpose. In conjunction with the workshop, SPORE Directors will be required to attend an administrative and planning meeting with program staff from the NCI.

9. **Other Provisions**
   If a SPORE application originates from an institution that is supported by an NCI Cancer Center Grant (P30), the following items should also be addressed (generally within the Program Description).

   a. Once a SPORE is funded, the Principal Investigator of the SPORE should become a senior leader in the Cancer Center. The Principal Investigator of the SPORE may or may not be the Cancer Center Director.

   b. Lines of authority should be clearly indicated such that the SPORE is an integral part of the Cancer Center but does not interfere with the P30 chain of authority. A letter of commitment which delineates these organizational relationships is required. This letter must be signed by the proposed Principal Investigator of the SPORE, as well as the Cancer Center Director.

   c. The applicant should discuss how the SPORE will interact synergistically with existing P30 programs in order to maximize both SPORE and Cancer Center research objectives. While the SPORE is expected to become an integral element within the NCI-designated Cancer Center, a distinct institutional commitment to the SPORE must still be maintained throughout the term of the SPORE grant (see Section E.2. above).

d. The resources (or cores) within the SPORE should not duplicate any available facility already in place and supported by another granting mechanism (e.g., P30, P01, U01, U10, DOD, etc.). Applicants can, however, use SPORE funds to augment pre-existing Cancer Center resources in order to direct these activities towards more effectively fulfilling the requirements of the SPORE. This is especially true of the SPORE tissue resource, which should be designed to prioritize the needs of SPORE investigators over those of others. The SPORE should also utilize the IRB, Data and Safety Monitoring Board(s), as well as clinical resources available throughout the Cancer Center whenever possible.

---

top

F. SUBMISSION REQUIREMENTS AND RECEIPT DATES

1. **Pre-application Consultation (Strongly Recommended)**
   NCI program staff strongly encourages each prospective applicant to schedule a pre-application consultation. The consultation should be scheduled four to six months in advance of the due date for submission and is intended to help the applicant **(along with one or more of his/her intended co-investigators)** understand the SPORE Program and discuss strategies for preparing a competitive application. NCI staff will clarify the intent of the guidelines, discuss funding trends, discuss potential alternative SPORE organizational structures and allowable resources, and describe the peer-review process. The applicant can define which issues would be most helpful to discuss and then work with NCI program staff to decide what information is most appropriate to provide. The following are examples of items that help NCI program staff understand the plans of applicants:

   - A brief description of the background and proposed responsibilities of the SPORE Director and key senior leaders of the SPORE.
   - A diagram showing the proposed reporting, programmatic, and advisory structure of the SPORE and
   - A brief description of the proposed translational research projects, along with their specific aims and the names of project leaders.
   - Estimated budgets for each component (i.e., full projects, resources, developmental/career programs) of the anticipated SPORE application.
   - A list of active peer-reviewed research grants, cooperative agreements, and contracts that form the research base of the scientific leaders of the SPORE.

2. **Letter of Intent**
   Although it is not required and does not enter into the review of an application, all prospective applicants are requested to submit a letter of intent no later than August 1, 2002. The letter of intent should include a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. This letter allows NCI staff to estimate the potential review workload and avoid conflict of interest in the review. Furthermore, NCI staff can make sure applicants are fully aware of all applicable NIH and NCI policies, meet eligibility requirements and understand the peer review process before the application is submitted.

   The letter of intent should to be sent to the following address:

   Organ Systems Branch

OCTR, ODDES, NCI
6116 Executive Blvd.
Suite 7013, MSC 8347
Bethesda, MD 20892

3. **Application Procedures**
The NIH application form PHS 398 (rev. 5/01) is to be used in applying for these grants. Application forms and guidelines are available through: most institutional offices of sponsored research, or from:

Division of Extramural Outreach and Information Resources
National Institutes of Health
6701 Rockledge Drive, Suite 6095
Bethesda, MD 20892-7910
Ph. (301) 435-0714
FAX (301) 480-0525
E-mail: grantsinfo@nih.gov

http://deainfo.nci.nih.gov/extra/pa/mechanism/p50.htm and the NIH Guide at
http://grants.nih.gov/grants/guide/index.html
preparing a SPORE application. On line 2 of the face page of the application form, the applicant should provide the Program Announcement (PA) number, the title "SPORE in Pancreatic Cancer", and check the YES box.

At the time of submission, the original signed application, including the checklist, should be sent along with three signed copies (without appendices) to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive
Room 1040, MSC 7710
Bethesda, MD 20892-7710
(use 20817 zip code for express service)
Ph. (301) 435-0715

Two additional copies of the application **and six copies of any appendices** must also be sent to:

Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Blvd., Room *8041, MSC-8329*
Rockville, MD 20852 (if express delivered)
Bethesda, MD 20892-8329 (if using US Postal Service)

APPLICATIONS HAND-DELIVERED BY INDIVIDUALS TO THE NATIONAL CANCER INSTITUTE WILL NO LONGER BE ACCEPTED. This policy does not apply to courier deliveries (i.e. FEDEX, UPS, DHL, etc.) (http://grants.nih.gov/grants/guide/notice-files/NOT-CA-02-002.html) This change in practice is effective immediately. This policy is similar to and consistent with the policy for applications addressed to Centers for Scientific Review as published in the NIH Guide Notice http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html.

The copies to the Center for Scientific Review (CSR) and the Division of Extramural Activities (DEA)

should be sent at the same time to assure that the NCI will be able to review the application along with others submitted for the same receipt date. The applicant is encouraged to keep documentation of their mailing date(s) rather than contact the CSR or DEA for confirmation of receipt. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique. Applications must meet all eligibility requirements as described above and must address all programmatic requirements (see ELIGIBILITY AND REQUIRED COMPONENTS, above) in these guidelines.

4. **Application Receipt Date**
   Applications for SPOREs in Pancreatic Cancer are due October 1, 2002. Applications will be accepted only by the specified receipt date. Incomplete applications will be returned without peer-review (see ELIGIBILITY AND REQUIRED COMPONENTS, above).

5. **Inclusion of Women, Minorities, and Children in Research Involving Human Subjects**
   It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

   All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

   The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

   All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at .

6. **URLS in NIH Grant Applications or Appendices**
   All applications and proposals for NIH funding must be self contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

7. **Required Education in the Protection of Human Research Participants**

Investigators proposing research involving human subjects are now required to demonstrate that they have been trained in the protection of human research participants according to the policy published in the NIH Guide for Grants and Contracts, June 5, 2000 (Revised August 25, 2000), available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. A continuing education program in the protection of human participants in research is now available online at http://cme.nci.nih.gov/.

8. **Public Access to Research Data Through the Freedom of Information Act**
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this RFA (PA) in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include info
9. rmation about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the

10. **Human Embryonic Stem Cells (hESC)**
Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

---

top

G. REVIEW CONSIDERATIONS

1. **Review Policies**
Upon receipt, applications will be reviewed for completeness by the CSR and the NCI program staff for adherence to the guidelines of this PA. Applications not adhering to the guidelines of this PA, and those applications that are incomplete as determined by CSR or by NCI program staff, will be returned to the applicant without review.

- Receive a written critique
- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- Receive a second level review by the appropriate national advisory council or board

2. **Application Receipt and Referral**
SPORE (P50) applications, like all other PHS applications, are received and initially processed by the NIH Center for Scientific Review (CSR). Following the current NCI referral guidelines, the application is assigned to NCI and subsequently to the Organ Systems Branch and SPORE program area. An SRA in the

Grants Review Branch in the NCI Division of Extramural Activities will be assigned to manage the review.

After application submission, all correspondence should be directed to the SRA. Applicants are expected to submit complete applications by the specified receipt dates. The decision on whether to accept additional supplementary documentation is that of the SRA.

3. **Review Procedures**
As the manager of the review process, the SRA serves as the resource for both applicants and reviewers with respect to NIH review policies, guidelines, rules, regulations, options available, procedures, etc. He or she ensures that the review is conducted in accordance with NIH and NCI policies. The NCI Program Director serves as a resource, as needed, concerning the history, intent and development of the program, changes in program direction, objectives and any other relevant programmatic matters.

The scientific merit of a SPORE application is assessed by the peer review committee. Review of a SPORE application will include participation of senior scientists with review experience, a broad perspective on cancer research, and a wide variety of expertise. Breadth is a necessary component of the review committee. Patient advocates also provide important points of view in regard to translational research conducted by SPOREs and therefore will also serve as members of this review committee. Applicants should take into account the fact that their application is reviewed by multiple individuals. Any piece of information that is critical to a particular project, resource, or program should be presented within the section designated for that activity (and not just within the overall "Program Description", for example).

Following assignment of a priority score by the review committee, action by the NCAB completes the peer-review process.

4. **Review Criteria**
The evaluation of applications is based on the following:

(a) Full Projects
Within the SPORE concept of translational research (see definition in Section I.B. above), reviewers will evaluate each research project using the five review criteria and additional factors noted below. Each criterion will be considered by the reviewers in assigning the overall merit score of the project, although a project does not need to be strong in all criteria in order to be viewed as meritorious.

(a.1) Significance
The importance of the research objectives to human pancreatic cancer and their likelihood of completion within the maximum five-year project period. For projects focusing on animal models or in vitro systems, the feasibility of reaching a human endpoint in the foreseeable future.

(a.2) Approach
The adequacy of the experimental design and methods to achieve the research objectives, as well as clear evidence of **co-leadership** by a scientist with a basic biological background, basic and/or applied scientist with a clinical research or population science research background in the conception, design, and proposed implementation of the project. Rationale for changing scientific direction and/or approach will also be evaluated for competitive renewals.

(a.3) Innovation
Originality and novelty of experimental concept, design, and/or approaches **as they relate to the**

(a.4) Investigators

The qualifications of the basic biological and more applied co-investigators to conduct the proposed research and the appropriateness of the time commitments of each co-investigator to conduct the project.

(a.5) Environment
The scientific environment in which the translational research work will be done and the unique features, if any, of the environment to support the proposed work. The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

(a.6) Human Subjects
The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

(a.7) Protections
The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

(a.8) Data Sharing
The adequacy of the proposed plan to share data.

(b) Shared Resources (Cores)

(b.1) Tumor Bank/Tissue Resource

- Adequacy of the proposed plan to develop and maintain a human pancreatic cancer tissue resource, store the tissue, and link the tissue with appropriate pathological, clinical, and family history data to maximize their potential use in translational research. If a consortium is proposed, adequacy of the plan to integrate samples and data from multiple sources. (Note: Use of human tissues in proposed research projects is encouraged but not required)

- Adequacy of the proposed plan to prioritize the distribution of tissues within and outside the SPORE.

- Evidence of experienced and available personnel dedicated to the activities of tissue collection, quality control of tissue specimens, tissue storage, tissue distribution, collection of initial and follow-up clinical information, data entry, and maintenance of database and computer networks.

- When appropriate, adequacy of the proposed plan to augment and/or complement any existing tissue resource supported by a Cancer Center Support Grant (P30) to avoid duplication and maximize productivity.

- Adequacy of the proposed plan to obtain informed written consent for all prospectively collected tissues and protect confidentiality.

- Appropriateness of the budget to conduct and integrate tissue banking activities.

(b.2) Other Resources

- Degree to which plans indicate that shared resources (will) effectively and efficiently support the research of the SPORE in a manner that can not be supported through other available

(institutional or outside) resources.

- When appropriate, adequacy of the proposed plan to augment and/or complement an existing shared resource supported by an NCI Cancer Center Support Grant (P30).
- Demonstration that the resource is essential to the success of the SPORE.
- Adequacy of qualifications and performance (if applicable) of resource directors.
- Appropriateness of requested budgets to conduct each resource operation.
- For family registries, adequacy of proposed plan to develop and maintain the registry (or participate in an existing registry), with appropriate follow-up data collection; if a consortium is involved, adequacy of the proposed plan to integrate data from multiple sources (Note: Use of family registries in proposed research projects is encouraged but not required).

(c) Developmental Research Program

(c.1) Adequacy of the process for attracting new ideas and pilot studies within and outside of the SPORE institution.

(c.2) Adequacy of the proposed process for continuously reviewing and funding a spectrum of pilot projects (e.g., research, technology development, resources) based on their relevance to translational research and potential impact on human pancreatic cancer.

(c.3) Appropriateness of the budget relative to the needs and demonstrated capabilities of the SPORE.

(d) Career Development Program

(d.1) Adequacy of the plan, in general, to sustain a significant activity for career development of translational research scientists, including both junior scientists beginning their research careers and senior scientists wishing to refocus their careers on translational research.

(d.2) Adequacy of the process for selecting candidates for independent careers in translational pancreatic cancer research.

(d.3) Adequacy of the procedures to seek out and include qualified minorities and women and persons with disabilities.

(d.4) Appropriateness of the budget (whether derived entirely from the SPORE or a combination of sources) relative to the proposed plans for sustaining a significant effort in career development.

(e) Overall Program Organization and Capability

(e.1) Scientific qualifications and involvement of the SPORE Principal Investigator as well as his/her demonstrated scientific and administrative leadership capabilities and time commitment.

(e.2) Adequacy of the planning and evaluation process to include: determining pancreatic cancer research productivity and translational potential of existing projects and resources; discontinuing activities of low productivity; initiating new activities in response to important pancreatic cancer research opportunities; establishing

(e.3) Adequacy of access to patients and populations for conducting current and projected therapeutic, prevention, detection and control research.

(e.4) A balance and diversity of research activities within a minimum of three scored projects.

(e.5)

(e.6) Plans for integrating SPORE research and resources with existing Cancer Center/Institutional programs (e.g., use of clinical data and safety management systems, biostatistical cores, etc.).

(e.7) Adequacy of tangible institutional commitments that will enable and facilitate the research objectives of the SPORE (e.g., special facilities, recruitments, discretionary resources such as dollars and space).

(e.8) Degree to which the organization and leadership of the SPORE promote and facilitate scientific interactions between projects, pilot projects, etc., and effective use of the SPORE infrastructure (e.g., tissue bank, other shared resources) in the conduct of research.

(e.9) Written assurance that SPORE interactions with commercial entities will uphold the principles of academic freedom, including the ability of SPORE investigators to collaborate freely and to send and receive biomedical research materials without restriction to other scientific researchers.

(e.10) Facilitation of technology transfer; management of the intellectual property rights of the SPORE under the requirements of the Bayh-Dole Act and NIH funding agreements.

(f) Interactions with Other SPOREs

(f.1) Adequacy of plans to promote and maintain communication and integration of scientific projects of mutual interest with other SPOREs; examples include the development of core resources that serve either the same organ site or multiple organ sites, as well as clinical or research activities performed in a multi-institutional setting.

(f.2) Willingness to interact with other SPOREs and with the NCI in sharing information and participating in committees to assess current scientific issues, research activities, and priorities.

5. **Overall Evaluation and Scoring of Applications**

A single numerical priority score will be assigned to the SPORE application as a whole after discussing all of the review elements listed above. The score will be based on the overall quality of the research projects (using the SPORE definition of translational research in Section I.B.) and career development and developmental research programs, the overall effectiveness and adequacy of shared resources, the overall program organization and capability, and the plans for and productivity of interactions with other SPOREs. Although primary emphasis will be placed on scientific merit and progress where applicable (competing

renewal applications), significant consideration will also be given to interdisciplinary interactions, potential for impacting on the disease, Inter-SPORE collaborations and institutional commitment.

The overall score will be weighted as follows:

60% scientific merit and translational potential of the research
15% evidence of multidisciplinary/team approaches in the conduct of research objectives
15% potential of the research to impact on the disease
10% institutional commitment

If a required component(s) of an otherwise meritorious SPORE application is of such low merit that it is not recommended for further consideration (NRFC) by the peer review committee, the entire application will also receive a NRFC.

6. **Summary Statements**
The findings and recommendations of the reviewers are summarized in a written report (i.e., Summary Statement) which conveys the evaluation of the P50 application. This Summary Statement is transmitted to the NCAB for second level review, to the NCI official file and to the appropriate NCI staff. NCI program staff will automatically send a copy to the principal investigator as soon as the final document is available.

7. **Award**
Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance to program priorities
The EC may consider funding a P50 application as a P20 planning grant. Applications considered for P20 awards will be funded on the basis of their scientific merit and NCI programmatic priorities.

The award and administration of the P50 and P20 grants are subject to the same policies and procedures as other research grants. These policies and cost principles are set forth in the current NIH Grants Policy Statement, other NIH and NCI issuances and Federal legislation and regulations.

---

top

H. INQUIRIES

For further clarification of the different topics contained in the present guidelines, individuals may contact the Organ Systems Branch by e-mail (nciosb-r@mail.nih.gov) phone (301-496-8528), or fax (301-402-5319).

Healthy People 2010
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. These Guidelines are related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

---

top

SECTION II. SPECIAL INSTRUCTIONS FOR PREPARING A COMPETING SPORE GRANT APPLICATION

These instructions provide information needed for the preparation of either a new or competing renewal grant

application for a Specialized Program of Research Excellence (SPORE). The application receipt dates are specified in the program announcement (PA) and "GENERAL SPORE GUIDELINES, Section I.F., above" prepared by the Organ Systems Branch, NCI.

A. GENERAL INFORMATION

General instructions for the preparation of NIH grant applications are contained in the PHS 398 research grant application instructions and forms (rev. 5/2001) and can be found at http://grants.nih.gov/grants/funding/phs398/phs398.html. This version of the PHS 398 is available in an interactive, searchable PDF format. Even though the application kit is intended primarily for a single research project grant (i.e. R01), many of the general instructions and forms also apply to SPORE grant applications. However, as outlined in Section I, SPORE grants have unique requirements and review criteria. Accordingly, the special instructions in this document were prepared for use along with the PHS Form 398 grant application kit.

---

top

B. DETAILED DIRECTIONS

1. **Face Page**
   The face page is the same as the face page (form page AA) in the PHS 398 kit. In item 1, enter the title "S PORE in Pancreatic Cancer". In item 2, insert the PA number, and enter the title "Specialized Program of Research Excellence". In item 3, indicate the name, degree, and position (or equivalent) title of the SPORE Principal Investigator. Complete the rest of the page according to the instructions in the application kit, including the signature of the appropriate institution official(s).

2. **Description, Performance Sites, and Key Personnel (Page 2)**
   Page 2 is the same as page 2 in the PHS 398 application kit. Provide a brief description of the proposed SPORE in the space provided, specifically addressing each project and proposed resource core. Fill in all the performance sites and all key professional personnel including all project and core leaders and key personnel of the Developmental Research and Career Development Programs, using continuation pages as required.

3. **Table of Contents (Page 3)**
   Instead of using form page 3 in the PHS 398 application kit, prepare a Table of Contents that identifies by page number all major parts of the SPORE application so that they can be readily located. When listing individual projects and core components, identify each by a project or core number, title and responsible investigator(s) in the order in which they appear in the application.

   It is recommended that all applicants follow a format similar to that outlined below:

   I. Face Page
   II. Description, Performance Sites, Key Personnel (PHS 398 Form Page 2)
   III. Table of Contents (PHS 398 Form Page 3)
   IV. Initial Budget (PHS 398 Form Page 4; see item 4 below)
   V. Summary Budget (PHS 398 Form Page 5; see item 5 below)
   VI.
   VII. Other Support (see item 7 below)
   VIII. Resources (see item 8 below)
   IX. Eligibility Statement (see item 9 below)
   X. Program Description (see item 10 below)
      A. Introduction
      B. Institutional Commitment
      C. Scientific and Administrative Leadership

D. Relationship to Cancer Center
E. Scientific Integration - Interactions and Collaborations
F. Cancer Patient Population
G. Translational Research Objectives
H. Planning and Evaluation Activities

XI. Research Projects (Minimum of four projects required; see item 11 below)
   A. For competing renewals, describe, outline the scientific accomplishments and discuss the potential impact on the disease for each project completed in the last grant period. Limit this
   B. Project 1
      1. Title Page with **Co-(Principal) Investigators**
      2. Abstract Page
      3. Budget/Budget Justification Pages
      4. Research Proposal (If an ongoing project, discuss scientific progress and adhere to the original five-year time frame)
      5. Human Subjects and Vertebrate Animals
   C. Project 2
      1. Title Page with **Co-(Principal) Investigators**
      2. Abstract Page
      3. Budget/Budget Justification Pages
      4. Research Proposal (If an ongoing project, discuss scientific progress and adhere to the original five-year time frame)
      5. Human Subjects and Vertebrate Animals etc.

XII. Core Resources (Tissue Core required; see item 12 below)
   A. Core 1
      1. Title Page with Director(s)/Leader(s)
      2. Abstract Page
      3. Budget/Budget Justifications
      4. Plan/Interactions/Progress (for competing renewals)
      5. Human Subjects and Vertebrate Animals
   B. Core 2
      1. Title Page with Director(s)/Leader(s)
      2. Abstract Page
      3. Budget/Budget Justifications
      4. Plan/Interactions/Progress (for competing renewals)
      5. Human Subjects and Vertebrate Animals etc.

XIII. Developmental Research Program (see item 13 below)
   1. Title Page with Director(s)/Leader(s)
   2. Budget/Budget Justification Pages
   3. Plan/Examples
   4. For competing renewals describe each project funded during the last grant period and the outcome of each project relative to the SPORE objectives.

XIV. Career Development Program (see item 14 below)
   1. Title Page with Director(s)/Leader(s)
   2. Budget/Budget Justification Pages
   3. Plan/Examples
   4. For competing renewals, denote individuals supported during the last grant period, their scientific accomplishments while supported by the SPORE, and how SPORE support has advanced their translational research careers.

XV. Checklist (see item 15 below)
XVI. Appendix Material (see item 16 below)

4. **Summary Program Budget for the Initial Budget Period**

Use form page 4 in the PHS 398 application kit to present the summary budget for the first year. For each category, show separately the total amounts requested for each research project and core.

If the grant application includes research activities that involve institutions other than the applicant organization, the proposed program represents a consortium effort. It is essential to explain the programmatic, fiscal, and administrative arrangements for such activities. These matters should be discussed in general terms in the program introduction, and more specifically within descriptions for pertinent projects. Include in the designated blocks on this page the total (direct and indirect) costs associated with such third party participation. The published policy governing consortia should be

5. **Summary Program Budget for Entire Project Period**
   Use form page 5 in the PHS 398 application kit to show the total SPORE budget requested for each of the five years. Justifications for increases in succeeding years should not be included here; they should be delineated in the **detailed** budgets for **individual** projects (as described below in item 11). Note that current NIH practice limits overall budget escalation per year to 3% cost-of- living. Also note that NCI policy for SPORE grants establishes an annual **direct cost cap of $1.75 million** and maximum annual **total cost cap of $2.75 million** for new and competing applications. Applications submitted for pancreatic cancer SPOREs may exceed these caps, but **only**
   banking and pancreatic cancer registries. In non-competing years, applications can exceed caps as a result of the standard cost-of-living increases or special supplements approved by the NCI.

6. **Biographical Sketches**
   Prepare biographical sketches as described in the PHS 398 application kit. Begin with the Principal Investigator/SPORE Director and then proceed in alphabetical order. Biographical sketches are required for all professional personnel participating in the individual SPORE projects and core(s). The "Biographical Sketch" form is provided as form page 6 in the PHS 398 application kit.

7. **Resources**
   Complete form page 8 of PHS 398 application kit, as instructed. If applicable, additional Resource pages should be provided in consortia projects or cores. An extensive discussion of the institution's commitment to the SPORE is also required in item 10b below.

8. **Eligibility Statement**
   In considerable detail, specifically address how this application meets the eligibility requirements under

9. **Program Description**

   a. *Introduction*
      Describe the purpose and intent of the research program; the overall breadth of the scientific capabilities of the program to address critical issues in human pancreatic cancer from basic laboratory to clinical to prevention and control research; the organization of the SPORE to maximize the potential of the institution to achieve translational research objectives.

   b. *Institutional Commitment*
      Describe how the institution will make the SPORE an area of high priority. Describe the space, personnel and all other resources that the institution will make available to ensure that the SPORE exists in an appropriate environment for conducting an effective translational research program. Outline plans for the commitment of future resources in space and personnel to strengthen the research capability of the SPORE. The application should describe how the institution will participate in overseeing research progress, identifying research needs, and generally assuming a high level of accountability for the success of the SPORE in achieving research goals and objectives.

c. *Scientific and Administrative Leadership*
Describe the authority, scientific experience, and administrative experience of the principal investigator to provide leadership and direction to the SPORE. Similarly, describe the responsibilities of other senior scientific leaders and administrators and their qualifications to meet these responsibilities. Describe the processes and chain of responsibility for scientific decision-making and day-to-day administration and management of the SPORE.

d. *Relationship to Cancer Center*
If the SPORE application is being submitted from an institution already designated as a NCI Clinical or Comprehensive Cancer Center, a special section under this heading should clearly delineate the relationship of the SPORE (P50) to the cancer center (P30) as noted under "ELIGIBILITY AND REQUIRED COMPONENTS, Section I.E.9," above. A statement signed by the appropriate institutional official(s), Cancer Center Director and SPORE Principal Investigator confirming and agreeing to this relationship must be included in the appendix.

e. *Scientific Integration - Interactions and Collaborations*
Specifically discuss how interactions will be maintained and fostered between basic and more applied researchers within the research projects to produce a truly collaborative program that takes maximum advantage of research opportunities. Describe how the program will operate to collectively maximize research objectives. Discuss the critical interactions with other scientists within and outside of the institution that are specifically proposed to enhance the overall research objectives of the SPORE.

Describe the involvement of any other research, academic or administrative entities outside of the applicant institution, and how these other entities enhance the research capability. This should include all programmatic, administrative and fiscal consortial arrangements and how the effects of geographic separation will be overcome to maximize critical scientific interactions.

Describe how the core resources will be integrated effectively into the program and into existing cores in the Cancer Center (if applicable) to maximize the research capability and effectiveness of the SPORE.

f. *Cancer Patient Population*
Describe how the clinical patient care and service resources will be integrated with the research activities of the SPORE. Delineate the number and distribution of stages of cancer patients relevant to this organ cancer SPORE that are routinely cared for and how this patient population will meet all current and anticipated research needs. If the care and service facility is not part of the parent institution, the consortial arrangements should be clearly stated and officially confirmed as noted

g. *Research Objectives*
It is critical that the application delineate in considerable detail how the program will focus on moving basic research findings into studies for improving the detection, diagnosis, treatment and prevention of human cancer, or moving clinical observations into the laboratory environment (see Section I.B. for SPORE DEFINITION OF TRANSLATIONAL RESEARCH). Describe how the SPORE will strengthen its research capability through the use of developmental research funds to explore innovative research ideas.

h. *Planning and Evaluation Activities*
Describe how the SPORE will measure research progress collectively, identify new innovative research opportunities that can take maximum advantage of the multidisciplinary, translational research approaches, and identify projects for termination that are not achieving their research

objectives.

Provide a plan of how the SPOREs can utilize the annual SPORE workshop most effectively for sharing data, identifying new research opportunities, and setting priorities for future research. Specifically, incorporate the SPORE workshop into the Planning and Evaluation process of your organization.

In all of the above, clearly distinguish how the SPORE will utilize internal and external advisors.

10. **Research Projects**

As previously described, for the purposes of this program, the NCI has defined translational research as follows: **"Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans AND/OR determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer"**. The term "interventions" is used in its broadest sense to include molecular assays, imaging techniques, drugs, biologicals and/or other methodologies that are relevant to the prevention, early detection, diagnosis, prognosis or treatment of cancer. Translational research in SPOREs is always founded on and directly connected to some aspect of human biology and may encompass any form of cellular, molecular, structural, biochemical, genetic, or other appropriate experimental approach.

SPOREs conduct early-stage interventions to establish the feasibility or proof of principle of specific approaches in cancer. All research projects whose goal is the development and testing of an intervention are expected to reach the feasibility testing stage in humans within the anticipated five-year period of grant support. Similarly, studies that seek to determine the biological basis for an observation in human cancer should do so within five years. SPOREs are not the place for definitive validation of new interventions, which are supported by other programs in several divisions of the NCI.

Questions regarding the definition of translational research and its applicability to specific research projects should be directed to OSB program staff (see INQUIRIES, Section I.H. above).

For each research project provide the following as noted below. Page limitations specified for individual (R01) grant applications in the PHS 398 application kit must be followed for individual project and core unit research plans. Unnecessarily long, wordy or confusing presentations are usually perceived as indicators of premature or poorly planned research.

a. A title page with a project number, a title for the project and the co-principal investigators on a plain piece of paper.

b. An "Abstract of the Research Plan" using page 2 of the PHS 398 application kit. The top section should contain a succinct summary of the research project. The bottom section should include performance sites and all key professional personnel as instructed.

c. Budget Pages
The detailed budget for the first 12 months and the overall budgets for each succeeding year for each research project should be presented using the PHS 398 application, form pages 4 and 5 Directions for completing these are on pages 11-13 of the instructions in the PHS 398 application kit. For each category or individual listed on form page 4, provide a rationale in the budget justification.

d. Research Plan
Following the budget pages, use continuation pages to address items 9a through 9i as explained on pages 14-19 of the PHS 398 application kit.

Page limitations are the same as those delineated in the PHS 398 application kit; no more than 25 pages should be used for sections a-d of the Research Plan for each project proposed within the SPORE application. The 25-page limit also applies to all other self-contained components of the application, e.g., each Shared Core Resource, the Developmental Research Program, and the Career Development Program.

e. Human Subjects
For projects involving human subjects, applicants are required to address the six points on pages 17-18 of the PHS 398 instructions. The six points are as follows:

1. Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age, range and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

2. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

3. Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. The informed consent form, which must have IRB approval, should be submitted to the PHS only if requested.

4. Describe potential risks (physical, psychological, social, legal or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

6. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

Plans for the recruitment of women, children, and members of minority groups and subpopulations into clinical studies must also be stated in this section. A completed table, formatted like the one shown on page 30 of the PHS 398 instructions must be included along with a description of the proposed subject population in terms of gender and racial/ethnic groups.

f. Vertebrate Animals
If applicable, provide a brief description of any animal protocol, along with an IACUC approval number in this section. The five points for vertebrate animals listed below (as well as on page 18 of the PHS 398 instructions) should be addressed:.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex and numbers of animals to be used in the proposed work.

2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the veterinary care of the animals involved.

4. Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize the discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

11. **Core Resources**

Core resources should not duplicate products or services that are fundamentally available through any other mechanism (including a P30 and P01) or national resources supported by the NCI. SPORE resources may, however, be used to augment an existing P30 resource to enhance its capacity to serve SPORE research objectives. Cores can be used for a small administrative component or for scientific resources that clearly enhance the specialized research of the SPORE. Cores for tissue procurement and/or family registries are not required to serve SPORE projects presented in the application, though such use is encouraged if adequate resources are already available. Cores in all other categories should serve at least one full project. For each Core Resource, whether administrative or scientific, provide the following information:

a. A title page with the Core Resource Number, a Core Resource Title, and Director/Leader on a plain piece of paper.

b. An abstract of the Core Resource, using page 2 of the PHS 398 application kit as described for research projects in item 11, above. The abstract should describe the nature and purpose of the resource.

c. Budget Pages

d. Resource Proposal

(d.1) Describe the nature of the resource and its importance to the specialized research of the SPORE.

(d.2) Describe the facilities available and the qualifications of the professional expertise assigned to operate the resource.

(d.3) Discuss projected use of the core by individual research projects within the SPORE and any SPORE collaborators within or outside of the parent institution.

(d.4) Describe the projected operation, placing special emphasis on cost effectiveness and/or quality control factors.

e. Human Subjects and Vertebrate Animals
If applicable, address the six points regarding human subjects on pages 17-18 of the PHS 398 instructions and include a Gender and Minority Inclusion table(s) as outlined on page 30 of the PHS 398 instructions. If vertebrate animals are being utilized, address the five points for vertebrate animal usage on page 18 of the PHS 398 instructions. Also include the IACUC approval number(s)

12. **Developmental Research Program** This program should primarily be used to promote the exploration of innovative ideas through the funding of pilot projects. It can, however, also be used to initiate a new shared resource, establish short-term collaborations, and/or contract services required by the SPORE. This required component of the SPORE must be maintained for the duration of the grant period. This section of the application should include:

a. A Title Page with "Developmental Research Program" on a plain piece of paper.

b. (b) Budget Pages

c. A program summary containing the following elements:

(c.1) A description of the process used by the SPORE for identifying and selectively funding innovative, pilot studies within and outside of the SPORE institution.

(c.2) A description of the process for continuously reviewing and funding a spectrum of pilot projects for their quality and importance to translational cancer research.

(c.3) Brief examples of projects that may be supported during the grant period.

(c.4) A description of the process by which projects will be (or have been) promoted to full translational research projects within the SPORE.

13. **Career Development Program**
This is a special fund available in a SPORE that can be used to prepare new investigators or established investigators for careers in translational cancer research. This section of the application should include:

a. A title page using instructions in item 13, above.

b. Budget Pages

c.

(c.1) Describe the process for selecting candidates and how the program will place special emphasis on recruiting qualified women and minorities.

(c.2) Provide a short description of prospective mentors who have experience in translational research and who will interact directly with chosen new or established career development candidates.

(c.3) Describe any candidates that have already been selected for support under this program and the rationale for these selections.

14. **Checklist** Complete the checklist as required in the PHS 398 application kit.

15. **Appendix Material**
The application should be a complete document that includes all essential information necessary for its evaluation. Additional appropriate material may be submitted as appendices. There is no page limitation on appendices. However, appendices should not be used to bypass page limitations in the application because only selected reviewers will receive copies of the appendices. Follow the guidance in the PHS 398 application kit on page 19 regarding appendices, in particular noting what types of material may be included in an appendix.

---

top

SECTION III. SUPPLEMENTAL GUIDELINES FOR PREPARING A NONCOMPETING CONTINUATION SPORE GRANT APPLICATION

A. INTRODUCTION

These instructions are supplemental to those provided with the Form PHS 2590 (rev. 4/98), "Application for Continuation of a Grant," which is required each year in order to receive continuing support. In general, you should follow the "Information and Instructions for Using Form PHS 2590 to Apply for Continuation of a Grant Award." **To avoid a gap in funding, non-competing continuation applications should be received 60 days prior to the anniversary date of the award.**
eligible for the streamlined non-competing award process (SNAP). Additional guidance important in the preparation of a SPORE continuation application is provided below.

---

top

B. GENERAL ISSUES

The NCI advocates flexibility and innovation in the use of SPORE funds to achieve translational research objectives and will administer these grants in that spirit. Nevertheless it is important to highlight and explain changes in the component budgets that differ significantly from the approved peer-reviewed budget levels of the original competing application. Areas requiring explanation and justification are as follows:

a. Any proposed increase or decrease in the level of effort of key personnel.

b. Substitution, addition, or deletion of key personnel (e.g., project leader, co-leader, resource director).

c. Redistribution of dollars among budget components (NOTE: this is encouraged in a SPORE when it is done to place greater emphasis on more promising *translational* research activities).

d. New research activities not included in the competing application and not peer reviewed (NOTE: this is encouraged, especially in the use of developmental funds, to pursue the feasibility of new hypotheses of potential importance to translational research).

top

C. PROGRESS REPORT SUMMARY

The Progress Report Summary portion of the PHS 2590 application (pages 7-9) should be used for each full and developmental project within the SPORE. Applications should also include the following:

1. **Scientific Achievement of the SPORE Program**
   Describe the single most significant translational research achievement in the last year of support. Indicate the project, the achievement, and its potential impact on human cancer in one or two paragraphs.

2. **Director's Overview**
   This is an important section in which the Director describes how the SPORE program is functioning in special ways to achieve translational research objectives. In this section address the following issues

   a. The levels at which applied researchers (e.g., clinical researchers, prevention and control researchers) interact with basic investigators in the design and implementation of research that is most likely to have an impact on human cancer (i.e., reducing incidence and mortality).

   b. The different ways in which the members of the SPORE team are working together and exchanging ideas.

   c. The specific research efforts that appear to be the most, as well as least, promising in achieving a translational research objective.

   d. New ideas for translational research that have been generated by the SPORE.

   e. New priorities affecting the distribution of SPORE research funds based on the research progress of existing projects and results obtained from the use of developmental funds.

   f. Important collaborative efforts established within and outside the SPORE institution, through use of developmental or supplemental funds, that increase the exploration of new translational research opportunities.

   g. By-products that have emerged from SPORE scientists, the SPORE environment and/or SPORE collaborative studies that have resulted in the submission of grant applications (e.g., R01s) which are likely to advance fundamental studies in this cancer site. Please list in tabular form grant applications that have been submitted, where and when submitted, and whether pending, funded or not funded.

   h. Formal Inter-SPORE collaborative research activities that have been initiated and/or completed.

   i. Special efforts to recognize unique research opportunities based on incidence and mortality rates in the community/region of the SPORE and/or to enhance the research capability of the SPORE through interactions with individuals, organizations, and institutions within the community.

   In all of the above, the intent should be to explain how the team of SPORE scientists at the basic and applied levels are pursuing research objectives using integrated, innovative, and flexible strategies and are maximizing the unique capabilities of SPORE support in achieving translational research objectives.

3. **Research Projects**

Adhering to the instructions provided in the PHS 2590 packet, please describe the following:

a. *Specific Aims (no more that 500 words)*
Briefly describe the specific aims of the project as actually funded and how basic/clinical interactions have been employed in the design, implementation, and interpretation of experiments. Provide a short rationale for any changes in specific aims that have occurred over the past year.

b. *Studies and Results (no more than 750 words)*
For the past year, describe positive or negative results associated with each specific aim that are important to the underlying hypothesis. For those projects that involve clinical trials, briefly describe the status of each trial.

c. *Significance*
Explain in lay terms the importance and intent of the research in terms of translational research objectives that may impact on the disease in a reasonable time span.

d. *Plans*
Summarize plans for the next year to pursue existing specific aims and/or new or modified aims that may have a greater impact on the translational research objectives of the SPORE.

e. *Publications*
Append a list of published, submitted, or accepted manuscripts from the past year that **pertain to this grant (i.e., those that acknowledge support from this grant)**. Provide one copy of each new manuscript.

f. Project-Generated Resources
If the research supported by this grant resulted in data, research materials (e.g., cell lines, DNA probes, animal models), protocols, software, or other information available to be shared with other investigators, describe the resource(s) and how it may be accessed.

All projects involving human subjects or tissue resources should include status of patient/specimen accrual and recruitment of gender and minorities where applicable. **An updated Gender and Minority Inclusion Table is required each year for each individual project**. This table is provided at the bottom of form page 5 of the PHS 2590 application. Final assessment of closed or completed studies and pertinent publications and reports should also be included. A protocol and IRB approval must be on file with the NCI prior to the initiation of any new clinical trials.

4. **Resources**

Describe progress in establishing and maintaining the high-quality operation of each resource outlined in the original competitive application. Discuss any structural, organizational, logistical, or administrative changes in the resource; problems that have developed in the operation of the resource, as well as use of the resource by members of the SPORE and by outside investigators where appropriate.

5. **Developmental Funds**
In reporting on the use of developmental funds, describe the following:

a. How the funds are being used in a flexible manner to explore new research opportunities and how

b. The research objectives of each current pilot project being explored with developmental funds.

c. The positive and/or negative findings for each project during the past year. A final report is required on projects whose SPORE funding ended during the past year. Brief descriptions of newly initiated

projects should also be supplied.

d. Projects in which developmental funds have stimulated new collaborative interactions with scientists within or outside the SPORE institution.

e. Pilot projects that have become full translational research projects within the SPORE or have resulted in research grant application of a more fundamental nature relevant to the cancer site (e.g., R01s).

6. **Career Funds**
Briefly describe how each individual, whether recruited from within or outside the institution and supported from SPORE resources, is being prepared to pursue a career in translational research. As appropriate, indicate the current research activities of individuals who received career support from the SPORE program in the past.

7. **Supplemental Funds**
A progress report is also required on all activities that were supported during the last year by supplemental funds provided through the SPORE program.

top

National Cancer Institute (NCI) National Institutes of Health (NIH) Department of Health & Human Services (DHHS) FIRSTGOV Your First Click to the U.S. Government Related Links